

REMARKS

The above referenced application has been reviewed in light of the Office Action mailed January 10, 2008. Claims 1-9, 12-22, 24 and 25 are currently pending in this application with Claims 1 and 12 being in independent form. In view of the remarks to follow, allowance of this application is respectfully requested.

In the Office Action, Claims 1-9, 12-22, 24 and 25 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,537,593 to Alchas in view of U.S. Patent No. 5,403,344 to Allen. Applicants respectfully submit that Alchas and Allen, either alone or in combination, fail to teach or suggest the claimed apparatus and that there is no reason, motivation, or suggestion in either Alchas or Allen to combine the two references.

Applicants respectfully submit that Alchas fails to teach or suggest a surgical needle including, *inter alia*, a “needle point being displaced a predetermined distance with respect to the longitudinal axis and wherein the predetermined distance is less than $\frac{1}{2}$ the x-dimension ‘ x_t ’ of the enlarged transition portion, and at least one side of the needled end portion being displaced by an angle α from a plane parallel to the longitudinal axis, the angle α being between about 2° and about 10° , wherein the side of the needled end portion displaced by angle α from the plane parallel to the longitudinal axis has a substantially continuous slope between the enlarged transition portion and the needle point,” as required by both independent Claims 1 and 12.

In the Office Action, it is asserted that these features are disclosed by Alchas. Specifically, it was asserted that the “line from 4 to 39 in Fig. 3 is not a perfect line, it

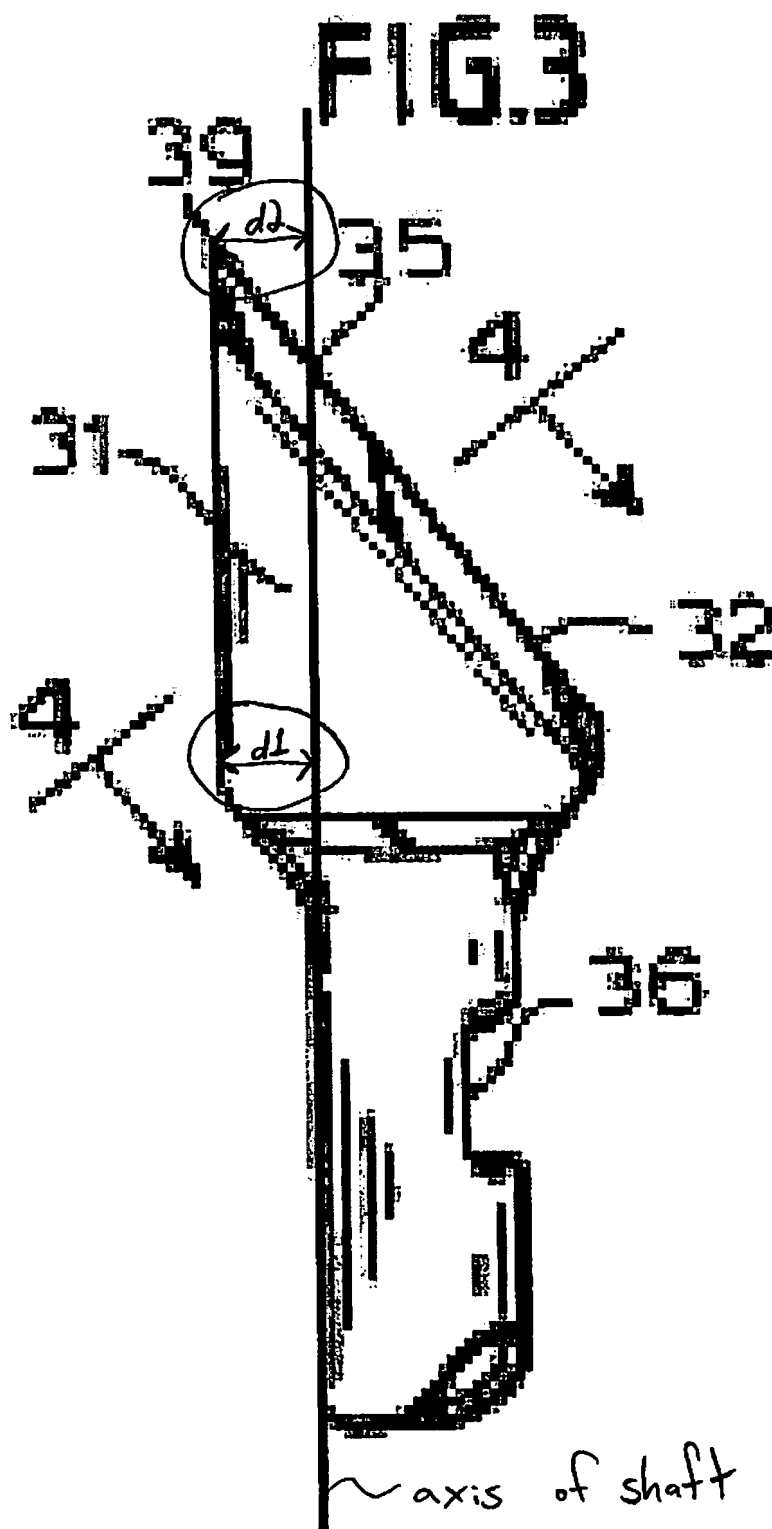
appears to be two degrees from the longitudinal axis.” This observation is improper.

MPEP §2125 states:

When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. See *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000)... However, the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of ordinary skill in the art. *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977).

None of the figures in Alchas show “at least one side of the needled end portion being displaced by an angle α from a plane parallel to the longitudinal axis, the angle α being between about 2° and about 10°.” Figure 3 of Alchas, an enlarged annotated version of which is reproduced below, which was relied on in the Office Action to disclose this feature, does not in fact show the claimed displacement. In annotated Figure 3 of Alchas, Applicants have noted that distance d1 measures the same as distance d2. Thus, the edge of the cannula (the line between 4 and 39) is parallel with the longitudinal axis defined by the shaft.

In addition, the specification of Alchas explicitly states, “[a] closed distal end 30 of the cannula includes a compressed planar or flat portion 31 which is substantially **parallel to a longitudinal axis 34** of the cannula” (column 5, lines 43-46; emphasis added; see also the distal portion of Figure 2 of Alchas, reproduced below). The disclosure of Alchas is otherwise “silent as to [the] dimensions” of the line between 4 and 39. Therefore, the Examiner’s assertion that “the line [of Alchas] from 4 to 39 in Fig. 3 is not a perfect line, it appears to be two degrees from the longitudinal axis,” is not only improper under MPEP §2125, but is also incorrect.



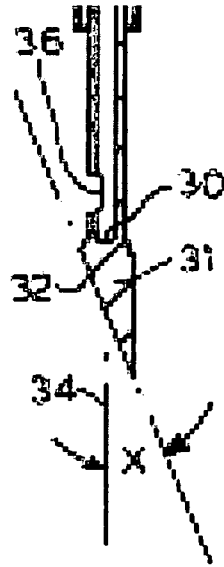


FIG. 2

Even assuming *arguendo* that Alchas does disclose that “line from 4 to 39 in Fig. 3 is not a perfect line, it appears to be two degrees from the longitudinal axis,” as asserted in the Office Action, Alchas still does not disclose that “at least one side of the needled end portion being displaced by an angle α from a plane parallel to the longitudinal axis” (emphasis added), as required by Claims 1 and 12. That is, Applicants’ claimed invention requires “three sides” and it further requires that one of the three sides “being displaced by an angle α from a plane parallel to the longitudinal axis.”

In the Office Action, the Examiner states, “Alchas does not have the needled end portion having three sides...” Thus, the asserted “line from 4 to 39” that “appears to be two degrees from the longitudinal axis,” even if accurate, which it is not, refers to an edge of the cannula and not a side of a needle.

Therefore, Alchas does not teach a “needle point being displaced a predetermined distance with respect to the longitudinal axis and wherein the predetermined distance is less than $\frac{1}{2}$ the x-dimension ‘ x_t ’ of the enlarged transition portion, and at least one side of the needled end portion being displaced by an angle α from a plane parallel to the longitudinal axis, the angle α being between about 2° and about 10° ,” as required by Claims 1 and 12.

In the Office Action, Allen is relied on to teach “the needled end portion having three sides (20) which intersect to define three cutting edges and terminate at a needle point (Fig. 3), each side including one sole pair of planar surface portions arranged in oblique relation to define a general concave appearance to each side (Fig. 4).”

Allen does not cure the deficiencies of Alchas, as Allen fails to disclose a “needle point being displaced a predetermined distance with respect to the longitudinal axis and wherein the predetermined distance is less than $\frac{1}{2}$ the x-dimension ‘ x_t ’ of the enlarged transition portion, and at least one side of the needled end portion being displaced by an angle α from a plane parallel to the longitudinal axis, the angle α being between about 2° and about 10° ,” as required by Claims 1 and 12.

Further, the Examiner has failed to overcome her burden of factually supporting her *prima facie* conclusion of obviousness. According to the strict guidelines of the MPEP, an Examiner must show a suggestion or motivation to modify the reference or to combine reference teachings; and a reasonable expectation of success.

Here, the Examiner’s combination of surgical suturing needles and hollow cannulas for piercing containers is improper. The main reference, Alchas, is directed to a hollow cannula for transferring liquid to and from a container having a penetrable stopper

that prevents coring of the stopper -- as opposed to a needle for penetrating tissue as required by Applicants' claims. As such, Alchas is directed to a completely different problem and attempts to solve the problem in a completely different manner than the present disclosure. Allen is directed towards a multi-faceted surgical needle. These differences make the combination of references improper. One skilled in the art of designing and making suturing needles, such as those described and claimed in Applicants' disclosure, would not gain any insight from the design of a hollow cannula, as its function is not even remotely similar (i.e., guiding a suture through tissue vis-à-vis removing fluid from or injecting fluid into a container).

Moreover, even if the combination of Alchas and Allen were proper, there is no indication that the combination would function the way the claimed invention does, thus there is no expectation of success. Therefore, there is no suggestion or motivation to combine references relating to needles used for suturing and references relating to hollow cannulas used for puncturing containers. Thus, the asserted combination of the two references is improper.

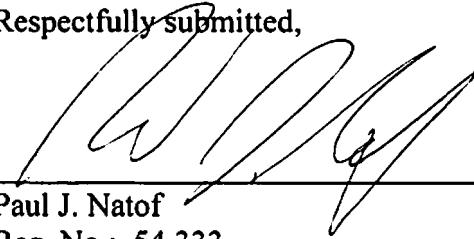
Accordingly, in view of the foregoing remarks/arguments, Applicants respectfully submit that the rejections of Claims 1 and 12, as being unpatentable under 35 U.S.C. §103(a) over Alchas in view of Allen has been overcome.

Since Claims 2-9, which depend from Claim 1, and Claims 13-22, 24, and 25, which depend from Claim 12, contain all of the limitations of Claims 1 and 12, respectively, for at least the reasons presented above regarding the patentability of Claims 1 and 12, Applicants respectfully submit that each of Claims 2-9, 13-22, 24, and 25 is also patentable over Alchas in view of Allen.

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In view of the foregoing amendments and remarks, Applicants submit that all of the claims are in proper format and are patentably distinct from the references of record and are in condition for allowance. The Examiner is invited to contact the undersigned at the telephone number listed below with any questions concerning this application.

Respectfully submitted,



Paul J. Natof
Reg. No.: 54,333
Attorney for Applicants

Carter, DeLuca, Farrell & Schmidt, LLP
445 Broad Hollow Road - Suite 225
Melville, New York 11747
Tel.: (631) 501-5700
Fax: (631) 501-3526

Mailing Address:
Covidien
60 Middletown Avenue
North Haven, CT 06473